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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,118	06/28/2000	R. C. Quijano	VENPROO.007C1	6405

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 05/27/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No. 09/605,118	Applicant(s) QUIJANO ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 30-36, 39-41, 51-69 and 71-117 is/are pending in the application.

4a) Of the above claim(s) 39-41, 53-58, 61, 62, 74-79, 82, 83, 95-100, 103, 104, 116 and 117 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 30-36, 51, 52, 59, 60, 63-69, 71-73, 80, 81, 84-94, 101, 102 and 105-115 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's previous election without traverse of Species A, Subspecies a, Species 1, and Subspecies I noted in Paper No. 21 is acknowledged.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 30-34,59,60,63-69,80,81,84-92,101,102,105-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Quijano et al. (5500014) in view of Richter et al. '734. Quijano et al. disclose valvular prostheses can be formed from a biological graft with a biological valve for defective blood vessels, col. 5, lines 10-15. Quijano also discloses the configuration depends on the intended use of the prosthesis (col. 8, lines 5-6) and also that valved conduits are needed to repair larger vessels, col. 14, lines 51-59. With respect to claims 34,67,88,112 the valves are fully capable of opening at pressures as low as 1mm Hg and remain sealably closed to withstand backflow pressure greater than 200 mm Hg. Quijano discloses that the tissue is fixed using an aldehyde, col. 10, lines 1-7. Quijano additionally discloses bovine or equine jugular veins can be used, col. 10, lines 12-14. However, Quijano does not disclose joining two segments for a bifurcated section of a damaged vessel. Richter et al. teach to join two conduits together at adjacent inflow ends (Fig. 10) forming a vascular prosthetic where the joined end has a cross-sectional area larger than any of the inflow ends of the conduits (Fig. 11) and the outflow ends can be used for a bifurcation. It would have

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been obvious to one of ordinary skill in the art to use the teaching of joining two conduits together as taught by Richter with the grafts of Quijano in order to provide a vascular prosthesis for use in blood vessels comprising branched vessels. Thus in view of the combined teachings the inflow end is suitable for attachment to a heart and the outflow ends are suitable for attachment to pulmonary arteries.

Regarding claims 35,36,68,69,89,90,113,114 Quijano as modified by Richter do not disclose the cross-sectional area of the inflow end of the graft being greater than 22 or 28mm. It would have been an obvious matter of design choice to have an inflow end with a cross-sectional area greater than 22 or 28 mm, since applicant has not disclosed that this diameter provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the dimension taught by Quijano or claims 35,36,68,69,89,90,113,114 dimensions because both ends perform the same function of providing an increased diameter at the inflow end, considering the typical size of an artery.

With respect to claim 92, it would have been an obvious matter of design choice to have an angle formed of less than about 30 degrees between vessels, since applicant has not disclosed that this angle provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the angle taught by Quijano modified by Richter or claim 92's angle because both angle cuts permit the ability to attach inflow ends to form a greater diameter inflow end.

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Claims 51,52,72,73,93,94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. '014 in view of Richter et al. '734 as applied to claim 30 above, and further in view of Ehrenfeld (5156619). Quijano et al. as modified by Richter is explained supra. However, Quijano in view of Richter do not disclose using stitching to form a seam in a bifurcated replacement vessel. Ehrenfeld shows (Figs. 3,5) that stitching in the form of single passes are used in attaching tubular conduits together for a graft. Ehrenfeld also teaches that stitching is done such that it is placed on an even continuous suturing surface, col. 3, lines 57-61. It would have been obvious to one of ordinary skill in the art to use stitching as the means to join graft segments of Quijano as taught by Richter in order to provide means of permanent attachment and reduce any chance of detachment of the joined segments.

Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. '014 in view of Richter et al. '734 as applied to claim 63 above, and further in view of Mobin-Uddin (5078735). Quijano et al. as modified by Richter is explained supra. However, Quijano in view of Richter do not disclose the angled slice less than 15 degrees at an inflow end. Mobin-Uddin show an angled slice in a graft for joining with another segment and the angle can be construed to be "about" 15 degrees. The use of "about 15 degrees" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited because *about* can mean $\pm 10\%$ or $\pm 0.5\%$. It would have been obvious to one of ordinary skill in the art to use the angled slice as taught by Mobin-Uddin to join graft segments of Quijano modified by

Richter in order to provide an angled slice for attachment with another angled cut conduit.

Response to Arguments

Applicant's arguments filed 3/24/03 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Quijano discloses the configuration of the prosthesis depends on the intended use of the device (col. 8, lines 5-6) and also that valved conduits are needed to repair larger vessels, col. 14, lines 51-59. The intended use of the Quijano prosthesis can include bifurcated areas based on this disclosure. Thus, one of ordinary skill would look at the bifurcated prosthetic devices available. In this case the Richter patent is being relied on for the teaching of joining conduits to form a bifurcated prosthesis for use in a bifurcation. Richter is not used to substitute any materials as Applicant's have misconstrued the Examiner's rejection. In response to Applicant's remarks about the rejection of claims 51,52,72,73,93,94, it should be noted that the base reference Quijano teaches a tissue material for the conduits, therefore with the teaching of Ehrenfeld it would be obvious to use stitching to join the conduits. Regarding the remarks about the rejection of claim 71, again it should be noted that the modification of Quijano and Richter was not to substitute materials and thus in combining with Mobin

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'735 (a graft, clearly relevant) it would be obvious to use the teaching of angled slices at 15 degrees for seams.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738

Brian E. Pellegrino
3/22/03



Bruce Snow

Primary Examiner